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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,552	12/02/2000	Kong-Hong Andy Choo	11445Z	3587

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Garden City, NY 11530

EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,552

Applicant(s)

CHOO ET AL.

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 15-20, 28, 30-33, 40-46 and 61-67 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7, 15-20, 28, 30-33, 40-46 and 61-67 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 27 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Claims 1-7, 15-20, 28, 30-33, 40-46, 61-67 are pending in the application.

This Office Action is in response to the Amendment filed on 4/11/05.

Response to Amendment

Acknowledgement is made of Applicant's amendment of the specification to comply with the sequence rule.

The rejection of claims 28, 30, 61, 64-67 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-7, 15-20, 28, 30-33, 40-46, 61-67 under double patenting is withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-7, 15-20, 28, 30-33, 40-46, 61-67 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 10/6/04 and further discussed below.

The rejection of claims 1-7, 15-20, 31-33, 40-46 and 62-67 under 35 U.S.C. 112 2nd paragraph is maintained for reasons set forth of the record mailed on 10/6/04 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-7, 15-20, 28, 30-33, 40-46, 61-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the amended claims (1, 28 and 61) now recite both structural and functional features of the claimed nucleic acid molecule comprising a neocentromere. Applicants further argue that the specification also discloses two clones, E8 and F2, which are derived from a human mardel 10 chromosome, in addition to the neocentromere having the sequence of SEQ ID NO:3. Applicants assert that the clones contain sequences of the NC-contig region of the mardel chromosome, as well as additional p' and q' sequence adjacent to the NC-contig region. Applicants assert that the skilled artisan would be able to envision nucleic acid molecules of at least 80kb that include a neocentromere other than SEQ ID NO:3 based on instant teaching. Applicants also argue that the law does not require a reduction to practice of every aspect of the claimed invention for the purpose of satisfying the written description requirement. Applicants thus conclude that the claimed invention satisfies the written description requirement.

The above arguments have been fully considered but deemed unpersuasive. The amended claims are drawn to an isolated nucleic acid molecule comprising a neocentromere which is derived from a eukaryotic chromosome and does not have any detectable alpha satellite DNA as determined by FISH, wherein said nucleic acid molecule is at least 80kb in length and hybridizes to SEQ ID NO:3 under high stringency conditions which comprise from about 31%-

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50% formamide and from at least about 0.01M-0.15 salt for hybridization, and at least about 0.01M-0.15M for wash, or is at least about 80% identical to SEQ ID NO:3, wherein said nucleic acid is capable of replicating, acting as extra-chromosomal element and segregating with cell division when introduced into a cell. The claims still encompass a large number of nucleic acid molecules which share some homology with SEQ ID NO:3, wherein said nucleic acid molecules are at least 80kb in length. Although the claims recites high stringency hybridization condition, the condition in which the hybridization is carried out (31%-50% formamide, .01-.15M salt) would still include nucleic acid molecules of unspecific binding. Further, nucleic acids having 80% homology with SEQ ID NO:3 (~80kb) also encompasses a large number of nucleic acids of which differs from each other up to 16kb nucleotide sequence. As such, this claimed genus may encompass nucleic acid of different function (i.e. with conformation that is not capable of function as centromere) or encoding proteins of different functions. Contrary to Applicant's assertion, the specification only discloses a neocentromere represented by the sequence of SEQ ID NO:3. The clone F2 has an insert of 75 kb in length, which does not fall within the limitation of the claims of at least 80kb in length. Further, the specification fails to disclose whether the E8 and F2 clones, which are derived from a human mardel 10 chromosome which contains the NC-contig region, hybridizes under stringent condition to SEQ ID NO:3, or is at least 80% homologous to SEQ ID NO:3. Moreover, the specification fails to demonstrate that such clones that comprise a neocentromere are capable of replicating, acting as extra-chromosomal element and segregating with cell division when introduced into a cell. The specification also fails to disclose which part of the sequence of SEQ ID NO:3 is critical or essential for its neocentromere function of capable of replicating and segregating with cell division when introduced into a cell.

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The structural and functional relationship is thus missing. Furthermore, in view of the broad genus claimed, the disclosure of the specifications fails to constitute a representative species. As such, the specification fails to describe the claimed genus a representative number of species by their complete structure and other identifying characteristics. Although the 112 1st paragraph statute does not require a reduction to practice of every aspect of the claimed invention, the statute requires the specification to describe the claimed invention with all of its claimed limitations. The instant specification fails to describe the claimed genus of nucleic acid molecules in such a way to convey one skill in the art that the inventors had possession of the claimed invention at the time the application is filed. Therefore, this rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 15-20, 31-33, 40-46, 62-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response to this rejection, Applicants assert that the amended claims do not include limitations that render the claim indefinite.

However, claims 1, 31, 33, 62, 63, 67 still recite the term “derived.” As discussed in the previous office action, this term renders the claims indefinite because the nature and number of derivative process is not known such that the metes and bounds of the claims cannot be established. Claims 2-7, 15-20, 32, 40-46, 64-66 depend on the above claims, thus are also indefinite. Therefore, this rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

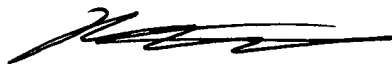
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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